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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09 359,300 | 07.21.1999 | MONIO H KUMAGAI | 08010137US07 | 2643 |

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LEFFERS JR, GERALD G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1636 | 29 |

DATE MAILED: 04.24.2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/359,300 | KUMAGAI ET AL. |
| | Examiner | Art Unit |
| | Gerald Leffers | 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

- 1) Responsive to communication(s) filed on 09 April 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 45 and 60-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 45 and 60-70 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review PTO-948
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) Interview Summary (PTO-413) Paper No(s) _____
 5) Notice of Informal Patent Application (PTO-152)
 6) Other

DETAILED ACTION

Continued Prosecution Application

The request filed on 4/9/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/359,300 is acceptable and a CPA has been established. An action on the CPA follows.

Receipt is acknowledged of three terminal disclaimers, filed as part of Paper No. 26 on 2/28/02, which have obviated rejections made over applications 09/359,297, 09/359/305 and 09/359,301 for obviousness-type double patenting.

Receipt is acknowledged of a declaration, filed by Dr. Della-Cioppa on 2/28/02 as Paper No. 25, concerning the metes and bounds of what constitutes a "functional gene profile". This declaration, filed under 37 C.F.R. §1.132, has been considered in full.

Finally, a response to the previous action has been received. The response was filed 2/28/02 as Paper No. 24 and includes an amendment of claim 45. Claims 45 and 60-70 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 60-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is vague and indefinite in that the metes and bounds of the phrase "functional gene profile" are unclear. **This rejection is maintained for reasons of record in Paper No. 19, mailed 8/30/01 and repeated below. Applicant's arguments filed in Paper No. 24 have been fully considered but they are not persuasive for the reasons given below in the Response to arguments.**

The phrase is defined in the specification (page 35, lines 3-12) as "The collection of genes of an organism which codes for a biochemical or phenotypic trait. The functional gene profile of an organism is found by screening nucleic acid sequences from a donor organism by over expression or suppression of a gene in a host organism. A functional gene profile requires a collection or library of nucleic acid sequences from a donor organism. A functional gene profile will depend on the ability of the collection or library of donor nucleic acids to cause over-expression or suppression in the host organism. Therefore, a functional gene profile will depend upon the quantity of donor genes capable of causing over-expression or suppression of host genes or of being expressed in the host organisms in the absence of a homologous host gene.". It is unclear from the claim language and from the definition given in the specification as to how many of the possible genes in an organism which "code" for a biochemical or phenotypic trait are required to be characterized by the claimed methods before a "profile" has been obtained. Would identification of only 2 genes of the many possible genes in either the host or donor organism which are associated with the determined phenotypic or biochemical change due to overexpression of heterologous nucleic acids in the host satisfy the criteria for a functional gene "profile" for that organism?

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The definition states that the functional gene profile will depend upon the quantity of donor genes capable of causing over-expression or suppression of host genes or of being expressed in the host organism in the absence of a homologous host gene, implying that the number of genes that needs to be characterized in order to generate a functional gene profile are all of the genes from an organism, host and/or donor, which are associated with a phenotypic or biochemical change due to expression of heterologous nucleic acids in the host. Would a "functional gene profile" be generated only when all of the genes from a donor or host organism are identified which are associated with a biochemical or phenotypic change upon expression of a heterologous nucleic acid in the plant host? If so, how would one know when all of the genes from either the host or donor organism associated with the biochemical or phenotypic change have been identified and the claim limitation met? It would be remedial to amend the claim language to clearly indicate how many of the possible genes from a donor or host organism associated with the determined phenotypic or biochemical change need to be identified in order to satisfy the claim limitation of being a "functional gene profile".

Response to Arguments

Applicant's arguments filed in Paper No. 24 have been fully considered but they are not persuasive. In Paper No. 45, claim 45 was amended to recite in step (f): "...identifying donor genes or plant host genes associated with said one or more phenotypic or biochemical changes; whereby a positive sense functional gene profile of said plant host or said plant donor organism is compiled." The response essentially argues: 1) the Summary of the Invention defines the claimed invention. 2) a functional gene profile is defined as a collection of genes of an organism which code for a biochemical or phenotypic trait. 3) the functional gene profile will depend upon

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the quantity of donor genes capable of causing over-expression or suppression of host genes or of being expressed in the host organism in the absence of the homologous host gene, 4) a functional gene profile does not have a fixed number of genes because it depends upon the quantity of donor genes capable of causing a biochemical or a phenotypic change, 5) the number of genes within a profile is finite, however, because it is limited by all of the genes in the genome of the organism, 6) each step of the claim is clear and definite, 7) there is no need to indicate the number of genes identified in order to satisfy the claim limitation of being a "functional gene profile", and 8) the declaration provided by Dr. Della-Cioppa illustrates fully how a functional gene expression profile can be compiled based upon claim 45.

The lines from the Summary of the Invention do not make clear the minimal number of donor and/or host genes that must be identified as associated with a particular biochemical or phenotypic change in order to obtain a "functional gene profile". The response reiterates several points taken directly from the definition provided in the specification and in the rejection. These points have been dealt with in making the rejection. For example, the contention that a functional gene profile is defined as a collection of genes of an organism which code for a biochemical or phenotypic trait implies that all of the genes from a donor or host organism, or both, must be identified in order to create a functional gene profile. While the examiner agrees that the number of potential genes in such a functional gene profile is finite and limited by the total number of genes in the donor or host organism, or both, it remains indefinite the minimal number of genes required to be identified as associated with a biochemical or phenotypic change in order to obtain a functional gene expression profile. What one practitioner is likely to consider a "functional gene profile" of an organism is likely to differ from investigator to

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investigator, especially in light of the indefinite definition provided by the instant specification. Therefore, there is in fact a need to amend the claim language to more clearly indicate what are the minimal number of genes that must be identified in order for one to satisfy the limitation of obtaining a "functional gene profile".

The declaration provided by Dr. Della-Cioppa addresses how the invention as currently claimed might be practiced. While the declaration might be useful in establishing the enablement of the instant specification for the claimed method, it is not on point with regard to the metes and bounds of what constitutes a "functional gene profile". The declaration does not clarify what are the minimal number of genes from the donor or host that must be identified in order to obtain a functional gene profile.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

H.R.
ggl
April 18, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo